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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/869,229

06/25/2001

Richard Ian Christopherson

DAVI139.001A

2287

500 7590 02/20/2007
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EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/869,229

Applicant(s)

CHRISTOPHERSON ET AL.

Examiner

Carolyn L. Smith

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1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2006 and 21 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58, 71, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58, 71, 73, 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendments and remarks, filed 8/9/06 and 11/21/06, are acknowledged.

Amended claims 58, 73, and 74 are acknowledged.

Applicant's arguments, filed 8/9/06 and 11/21/06, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 58, 71, 73, and 74 are herein under examination.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58, 71, 73, and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER

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Applicant points to written support for amended limitations on pages 12, 13, 22, 33, 39, 40, and 42. There does not appear to be adequate written support for the limitation “antigen-binding derivatives” (claim 58, line 3) and “antigen-binding derivative” (claim 58, line 6). While the specification recites “functional derivatives” (page 13, first paragraph) and “antigen-binding parts” (page 33, second paragraph), this does not provide adequate written support for “antigen-binding derivatives” and “antigen-binding derivative” which differ in scope. For example, an “antigen-binding part” is a fragment (up to and including the whole antibody) that comprises a Fab region which does not define what a derivative is.

Because the introduction of “antigen-binding derivatives” and “antigen-binding derivative” does not appear to have adequate written support in the specification, claims, and/or drawings as originally filed, this phrase is considered to be NEW MATTER. Claims 71, 73, and 74 are also rejected due to their dependency from claim 58. This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58, 71, 73, and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

LACK OF WRITTEN DESCRIPTION

Claim 58 recites the limitation “the cell surface marker antigens are selected from the list in Table 4” which lacks written description. According to the specification, a suspension of each type of cells (CEM, Raji and NB4) listed in Table 4 was exposed to an array of antibodies, and the binding was scored. The antibodies in the far left column of Table 4 cannot be interpreted to be cell surface marker antigens, since they are fixed to the array. Each cell type presumably has different antigens which are bound to the array, or there would be no scores. However, the Table does not clearly describe what those antigens ARE; i.e. there is a lack of structural description, sequence, chemical formula, or other relevant information, such that one skilled in the art would not be apprised that Applicant actually had possession of the ANTIGENS, as opposed to simply knowing that SOMETHING on the cells was bound by each antibody. Therefore, the limitation above does not meet the written description provision of 35 USC 112, first paragraph. Claims 71, 73 and 74 are also rejected due to their dependency from claim 58. This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58, 71, and 73-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 58 (lines 3 and 6) and 71 (lines 2-3) recite the term “derivatives” or “derivative” which is vague and indefinite. It is unclear what “derivatives” or “derivative” of an immunoglobulin is intended to be. Clarification of this issue via clearer claim wording is requested. Claims 71, 73, and 74 are also rejected due to their dependency from claim 58. This rejection is maintained.

Applicant argues that the claims read in light of the specification particularly point out and distinctly claim certain embodiments of the invention. This statement is found unpersuasive because while the claims can be read in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant argues that the amendments submitted render the rejections moot and summarize the invention. This statement is found unpersuasive as the rejection above still lacks clarity for the reasons given above.

Claim 58 recites the phrase “different immunoglobulin molecules specific for different cell surface antigens” which lacks clarity. It is unclear if Applicant intends to mean that each immunoglobulin (of the many on the array) is specific for ONE antigen, that an immunoglobulin may be specific for many antigens wherein there are many immunoglobulins on the array, or that

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many different immunoglobulins are specific for a single antigen. It is noted that earlier in the claim, Applicant limited an immunoglobulin on a specific portion of the array to be specific for a single antigen which makes the issue above even more confusing. Clarification of this issue via clearer claim wording is requested. Claims 71, 73, and 74 are also rejected due to their dependency from claim 58. This rejection is necessitated by amendment.

Claim 58 recites the limitation "the cell surface marker antigens are selected from the list in Table 4" which lacks clarity as Table 4 does not list any cell surface marker antigens. Table 4 has a column listing antibodies, not antigens. Clarification of this issue via clearer claim wording is requested. Claims 71, 73, and 74 are also rejected due to their dependency from claim 58. This rejection is necessitated by amendment.

Claim 58 recites the limitation "the immobilized immunoglobulins" in line 10. There is insufficient antecedent basis for this limitation in the claim. It is noted that the first part of instant claim 58 recites "immunoglobulin molecules, or antigen-binding derivatives thereof" whereas the latter part of the claim recites "immunoglobulins". Clarification of this issue via clearer claim wording is requested. Claims 71, 73, and 74 are also rejected due to their dependency from claim 58. This rejection is necessitated by amendment.

Claims 71, 73, and 74 recite the limitations "the immunoglobulins, or derivatives thereof" (claim 71, lines 1-3) and "the immunoglobulin molecules" (claims 73 and 74). There is insufficient antecedent basis for these limitations in the claims as there is previous mention of "immunoglobulin molecules, or antigen-binding derivatives thereof" in claim 58 which differs from "immunoglobulins, or derivatives thereof". Furthermore, it is unclear if "the immunoglobulin molecules" of claims 73 and 74 are referring to the first or second part of

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instant claim 58 (see rejection above). Clarification of this issue via clearer claim wording is requested. This rejection is necessitated by amendment.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28,

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1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (571) 272-0781.

February 11, 2007

A handwritten signature in black ink, appearing to read 'Carolyn Smith', with a stylized flourish at the end.

Carolyn Smith
Examiner
AU 1631